

12-11-03

10619847

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 7/46, 9/00, 9/20, A61L 9/02, A01N 25/20, A61K 9/16, 35/78	A1	(11) International Publication Number: WO 99/48469 (43) International Publication Date: 30 September 1999 (30.09.99)
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(54) Title: COMPOSITION FOR AROMA DELIVERY (57) Abstract Disclosed is a composition for delivering aroma comprising (a) an aromatic ingredient; (b) an exothermic ingredient; and (c) a pH adjusting agent; wherein the aroma is delivered when water is added to the composition.		

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COMPOSITION FOR AROMA DELIVERY

5

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FIELD

The present invention relates generally to a composition for delivering aroma. More particularly, the present invention relates to a composition for aroma delivery that is generated by an exothermic reaction.

15

BACKGROUND

Aromatic volatile components have been widely used in variety of products, including pharmaceutical products. Certain types of aromatic volatile components (e.g., menthol, eucalyptus oil, camphor, thymol) are known for treatment and therapy of common colds to relieve congestion and blocked nose. Many consumers suffering from colds or allergies and having some associated symptoms, for example, blocked nose and cough, tend to use pharmaceutical products made with such aromatic volatile components. These pharmaceutical products are commonly used by inhaling aroma vapours along with water vapours to relieve blocked nose, cough, and other cold or allergy symptoms. Generally, the vapours are generated by using hot water or steam.

Recently, another usage of aromatic volatile components has become increasingly popular. Consumers with mental stress often prefer to be in perfumed environments as a way to decrease stress. Due to their ability to induce relaxation and relief of mental stress, certain aromatic volatile components have become popular for treatment and therapy of such stress. These aromatic volatile components (e.g., cineol, jasmine, lavender oil) are known for providing fragranced environments in aroma therapy, as aromatic fragrance components. Herein, "aroma therapy" refers to a therapy which is for mental treatment, getting away from or releasing stress and, inducing relaxation, especially to ease mental stress. A conventional aroma therapy is by an

inhalation of aroma vapours. Aroma is generated from the aromatic fragrance components by using hot water in combination with aromatic actives, or by heating a vessel, for example a pot or a plate, in which aromatic fragrance ingredients and water are placed. Consumers, however, tend to become
5 frustrated with such methods of use, *i.e.*, heating water for aroma vapours and/or steam inhalation, and with cleaning messy vessels due to oily or waxy bases used for aroma generation after the inhalation of aroma vapours.

Certain exothermic reactions have been previously used for the purpose of generating heat or increasing temperature. A variety of products using
10 exothermic reactions are known, for example, in food products (*e.g.*, self-heating meal modules, see Taub et al. U.S. Patent 5,517,981), pharmaceutical products (*e.g.*, body warmers, see Sahara, U.S. Patent 5,220,909), or smoking articles (*e.g.*, cigarette, see Potter et al. U.S. Patent 4,955,399).

Based on the foregoing, there is a need for a composition for aroma
15 delivery that is convenient and readily usable, and which provides pleasant and/or therapeutic aromatic vapours by using an exothermic reaction.

SUMMARY

The present invention is directed to a composition for aroma delivery
20 comprising: (a) an aromatic ingredient; (b) an exothermic ingredient; and (c) a pH adjusting agent; wherein the aroma is delivered when water is added to the composition.

The present invention further relates to a composition for aroma delivery comprising: (a) an aromatic ingredient selected from the group consisting of an
25 aromatic active, an aromatic fragrance ingredient, and mixtures thereof; (b) first granules comprising an exothermic ingredient and a first carrier; and (c) a second granules comprising a pH adjusting agent and a second carrier; wherein the aroma is delivered when water is added to the composition.

These and other features, aspects, and advantages of the present
30 invention will become better understood from a reading of the present disclosure.

DETAILED DESCRIPTION

While the specification concludes with claims particularly pointing out and distinctly claiming the invention, it is believed that the present invention will be
35 better understood from the following description.

All percentages and ratios used hereinafter are by weight of total composition, unless otherwise indicated.

All measurements referred to herein are made at 25°C unless otherwise specified.

5 All percentages, ratios, and levels of ingredients referred to herein are based on the actual amount of the ingredient, and do not include solvents, fillers, or other materials with which the ingredient may be combined as a commercially available product, unless otherwise indicated.

10 All publications, patent applications, and issued patents mentioned herein are hereby incorporated in their entirety by reference. Citation of any reference is not an admission regarding any determination as to its availability as prior art to the claimed invention.

"Comprising" means that other steps and other components which do not affect the end result can be added. This term encompasses the terms
15 "consisting of" and "consisting essentially of."

The present invention relates to a composition for aroma delivery comprising: (a) an aromatic ingredient; (b) an exothermic ingredient; and (c) a pH adjusting agent; wherein the aroma is delivered when water is added to the composition.

20 Preferably, the temperature generated by the reaction of the exothermic ingredients with water is in the range of from about 40°C to about 100°C, more preferably from about 40°C to about 70°C. The specified temperature generated is achieved by the combination of the exothermic ingredients and water. Without being bound by theory, it is believed that such temperature range is suitable for
25 volatilizing aromatic ingredients including an aromatic active compound, and an aromatic fragrance compound.

In a preferred embodiment, the composition can deliver aroma by steam which may be generated by the temperature increase resulting from on the exothermic reaction with water.

30 A. Aromatic ingredient

The composition of the present invention comprises an aromatic ingredient. "Aromatic ingredient" herein refers to an ingredient which volatilizes due to the temperature generated by the reaction of the exothermic ingredients with water, and delivers aroma to the user. The aromatic ingredients useful in

the present invention include an aromatic active ingredient, an aromatic fragrance ingredient, and mixtures thereof.

The aromatic ingredient may be provided in any form, for example as an oil or as a water-oil emulsion. For example, in one embodiment, a kit product using the method of the present invention has two chambers, wherein one chamber contains an aromatic ingredient in emulsion, and another chamber contains an exothermic ingredient and a pH adjusting agent.

"Aromatic active ingredient" herein means an ingredient which is specially used for a medical therapy. The aromatic active ingredient can include any ingredients which are conventionally used as actives for medical treatment, for example, various aromatic actives which may be volatile and useful for treatment of colds, allergy symptoms, and blocked nose in various over-the-counter products. These aromatic actives can be in solid or liquid form.

Nonlimiting examples of the aromatic active ingredient include menthol, eucalyptus oil, camphor, thymol, turpentine oil, l-desoxyephedrine, bornyl acetate, and mixtures thereof.

"Aromatic fragrance ingredient" herein means an ingredient useful in aroma therapy for mental relaxation. Exemplary of the aromatic fragrance ingredients of the present invention include peppermint oil, spearmint oil, lavender oil, citronella oil, lemon oil, orange oil, sandalwood oil, and mixtures thereof.

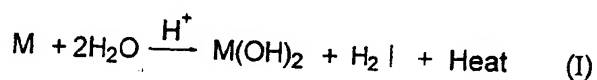
In certain embodiments, the aromatic active ingredient may further provide preferable fragrance in addition to the vapours for medical treatment purpose.

B. Exothermic ingredients

The composition of the present invention comprises an exothermic ingredient. "Exothermic ingredient" herein means an ingredient which is used for a reaction, called an exothermic reaction, to generate heat on reaction with water. The exothermic ingredients useful in the present invention can be any ingredients which are conventionally used for generating heat on reaction with water, and are available for use in pharmaceutical areas. The exothermic ingredients useful herein include a metal or a metal oxide.

The metals of the present invention include, for example, magnesium and sodium, preferably magnesium. The preferred metal oxides herein are calcium oxide.

Mechanisms of the exothermic reaction using metals differ from the reaction using metal oxides. Theoretically, the exothermic reaction of metal with water requires the presence of an acidic medium. The mechanism of the metal based exothermic reaction is that one mole of metal reacts with two moles of water in the presence of hydrogen ion, thereby one mole of metal hydroxide is derived, with the heat generation enabling volatilization of the aromatic ingredients. The following is an example of the exothermic reaction of the present invention using metal as the exothermic ingredient.



As shown above, the exothermic reaction (I) using metal with water derives a metal hydroxide with evolution of hydrogen gas. The hydrogen gas is evolved as bubbles and tends to give effervescence, leading to improve aesthetics. It is believed that the hydrogen gas may help the delivery of aroma and give a signal to the user as to the progress of the reaction of the exothermic ingredients with water. At the time when the exothermic reaction is substantially completed, the amount of bubbles evolved decreases.

The quantity of water added based on the exothermic reaction (I) is from about 1:20 to about 1:100, preferably 1:20 to 1:50 to the ratio of metal by weight for generating the temperature appropriate to volatilize the aromatic ingredients. For example, a composition for delivering aroma including about 0.1gm of metal is prepared and by adding about 5 ml (mgs) of water, a maximum temperature of about 68 degC. is generated for volatilizing the aromatic ingredients.

Preferably, the metal is of a high purity, and particularly when the aroma delivery is limited to occur using a large scale exothermic reaction (e.g., four times the amounts of metal and of water shown in the examples herein, as may be useful for providing aroma delivery in a room). It is believed that large scale exothermic reactions, particularly the reaction using magnesium, may cause off-odor or less odor reaction when the metal is of insufficient purity.

When metal oxide is the choice for the exothermic reaction to deliver aroma in the present invention, one mole of water is needed for the reaction with one mole of the metal oxide. In this case, there is no need for the presence of acids such as hydrogen ion for the exothermic reaction. As in the case of reaction (I), one mole of a metal hydroxide is derived, with the appropriate

temperature generation to volatilize the aromatic ingredients. The following is an example of the exothermic reaction using metal oxide.



5 No gas is evolved by the reaction (II). However, for giving the same aesthetic bubble effect as the hydrogen gas generated by the reaction (I), the exothermic reaction using metal oxide may include an effervescent agent.

The quantity of metal oxide to water based on the exothermic reaction (II) is at least from about 1:2 to about 1:15 by weight, preferably from about 1:2 to about 1:5, for generating the temperature for volatilization of the aromatic ingredients. For example, a composition for delivering aroma including about 10 1gms of metal oxide is prepared and by adding about 5 ml (mgs) of water, a maximum temperature of about 67 degC. is generated for volatilizing the aromatic ingredients.

C. pH adjusting agent

15 Herein, "pH adjusting agent" means a component which is useful for neutralization of the metal hydroxide derived by the exothermic reaction of the present invention described by reactions (I) and (II). It is recognized that these metal hydroxides derived from the exothermic ingredients with water tend to provide an undesirable alkaline pH condition, probably a pH of more than about 20 10. Generally, such pH condition is not safe. Therefore the pH adjusting agent is added to neutralize the metal hydroxides generated during the reaction. The following is a reaction for neutralization.



25 The pH adjusting agent useful herein includes any of the acids used for conventional neutralizations. Exemplary of the pH adjusting agent herein are citric acid, oxalic acid, and tartaric acid.

The pH adjusting agent can be added such that the conditions of the composition after aroma delivery are slightly acidic, preferably a pH of from about 3 to about 7. Total amount of the pH adjusting agent to the exothermic ingredients herein may be in the ratio from about 1: 3 to about 1: 6 by weight of 30 the composition. When metal is used as the exothermic ingredient, the weight ratio of the metal to the pH adjusting agent is preferably at least about 1 : 6.

When metal oxide is the exothermic ingredient, preferably the pH adjusting agent is at least about 1 : 3 by weight ratio.

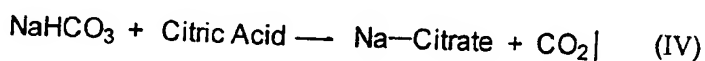
D. Additional ingredients

5 The composition of the present invention can further comprise additional ingredients selected from the group consisting of a carrier, a effervescent agent, a binding agent, a coloring agent, a tableting aid, and mixtures thereof. In embodiments comprising tablet, powder, or granules, the additional ingredients are preferably in a solid form to facilitate operating flowability and product stability.

10 The additional ingredients must be of sufficiently high purity and of sufficiently low toxicity to obtain the desirable quality for aroma delivery. Additional ingredients other than described below that are useful for the present invention further include, for example, diluents such as glucose, mannitol and directly compressible sugar; stabilizing agents such as agar, pectin, gums and
15 starches; antioxidants such as ascorbic acid and BHA; preservatives such as potassium sorbate and sodium benzoate, and the like; as well as other non-toxic compatible substances used in pharmaceutical formulation.

1. Effervescent agent

20 The composition of the present invention, especially those using the exothermic reaction (I) to vaporize aromatic ingredients, can evolve gases as discussed above. However reaction (II) does not provide bubbles, but sometimes it may be desirable to have bubbles, for example, for aesthetic purposes. "Effervescent agent" herein means any carbonate salt that provides bubbles when reacted with acid. Generally, the effervescence is evolved by the
25 reaction of a carbonate source with an acidic source, for example, in the combination of a carbonate salt and a carboxylic acid. Any ingredients which would be useful conventionally as an effervescent agent in the pharmaceutical area may be acceptable herein. The effervescent agent of the present invention can be selected depending upon compatibility with other components, particularly
30 the pH adjusting agent which reacts with the effervescent agent. The preferred effervescent agent herein is sodium hydrogencarbonate. The following is one embodiment of the reaction using sodium hydrogencarbonate with citric acids as acidic sources.



The carbon dioxide is evolved by the reaction (IV) to provide effervescence.

2. Carrier

The compositions of the present invention, especially those which are in tablet form, may include a carrier. The carrier useful for the compositions herein can be any which is available and conventionally used in pharmaceutical compositions. The carrier can be selected depending upon the compatibility with all of the ingredients included as well as the desired characteristic of the composition. Preferably, the carrier suitable herein is sugar.

The carrier may be added in a variety of forms depending on the form of the composition, preferably the carrier in solid form. For example, when the composition is in tablet form, the carrier may be mixed with other ingredients such as the exothermic ingredient and the pH adjusting ingredient during granulation.

The carrier is present at an effective level, preferably at a level of from about 10% to about 70% by weight of the composition. Preferably, the carrier may be added to each of main ingredients such as the exothermic ingredient and the pH adjusting agent separately for making granules to facilitate the process of tableting (e.g., granules containing the exothermic ingredient and the carrier; granules containing the pH adjusting agent and the carrier.) Preferably, the ratio of such ingredients to the carrier is about 50:50.

3. Binding agent

The compositions for the present invention may also include a binding agent. Inclusion of a binding agent is particularly useful to bind the components used for tablet forms of the composition. It is believed that insufficiencies in binding ability tend to cause compositions in tablet form, and especially those having a disc type shape, to break off into two pieces along the diameter during the manufacturing process. This splitting of the tablet is commonly referred to as "capping." The levels and types of binding agent are selected depending upon compatibility with other components, and desired characteristic of the final product.

Examples of useful binding agents include sugar, sugar alcohols, starches such as starch paste and pregelatinized starch, polyvinylpyrrolidone, cellulose derivatives, gelatin, gums, and mixtures thereof. In certain embodiments, especially the tablets, the binding agent and the carrier may be made of the

same material. Alternatively, the binding agent and the carrier may be altogether different. It is believed that the binding agent contributes to stability of the granules when added in the process of making granules.

The binding agents may be present in an effective amount, preferably from about 0.1% to about 10% by weight, more preferably from about 0.5% to about 3%.

4. Coloring agent

The composition including the method of the present invention may further include a coloring agent. The coloring agent may be present at an effective level, preferably from about 10 ppm to about 500 ppm, more preferably from about 20 ppm to about 250 ppm by weight.

5. Tableting aids

When the composition of the present invention is in tablet form, tableting aids can be added in order to facilitate forming the tablets. Herein, "tableting aids" refers to an ingredient that is added to the granules in small quantities to improve flowability to the granules, to reduce friction, and/or to ease removal of the tablets from the tableting machine. The tableting aids useful herein include, for example, magnesium stearate, stearic acid, aerosol, talc, and mixtures thereof. The tableting aid of the compositions of the present invention, is preferably present in an amount sufficient to prevent the tablet from breaking into two pieces, preferably from about 0.1% to about 8%, by weight of the tablet.

E. Granulation

Preferably, the composition of the present invention can be provided as a mixture of granules, especially the compositions in tablet form. Such compositions prepared from the granules and compressed the granules into tablet tend to generate suitable temperature for aroma delivery, thereby provide pleasant aromatic vapours.

Generally, granules can be handled readily during manufacturing. For example, granules provide an uniform mixture and distribution of ingredients into the composition, and facilitate the compression of ingredients into tablets. Due to the uniform distribution of ingredients, the composition herein produced by granules tends to contact with water effectively for causing the exothermic reaction to generate the desirable temperature and deliver the aromatic ingredient.

The composition of the present invention can comprise mixtures of granules. Especially useful are mixtures of granules comprising a carrier with the exothermic ingredient or a carrier with the pH adjusting agent.

5 First granules are obtained from the exothermic ingredients combined with a first carrier. The ratio of the first carrier to the exothermic ingredient is from about 30:70 to about 70:30, preferably 50:50 by the weight of the first granules.

Second granules are prepared by combining the pH adjusting agent with a second carrier. The ratio of the second carrier to the pH adjusting agent is from about 30:70 to about 70:30, preferably 50:50 by the weight of the second
10 granules.

The first carrier and the second carrier, which are used for the first and the second granules, can be the same carrier or different carriers. When the composition includes one carrier, the carrier may be proportionally included in the first granules and in the second granules. When the composition include more
15 than one carrier, each carrier may be separately added to the first and the second granules, or may be premixed and then proportionally included in each of the first and the second granules.

The granules herein may further include a binding agent. The binding agent can be the same as those discussed above or may be different
20 ingredients. It is believed that inclusion of certain binding agents may cause the temperature generated by the reaction to be somewhat lower, because of slow dissolution of the composition. The levels and types of the binding agent are selected depending upon the character of the carriers, compatibility with other components, and desirable characteristic of the final products.

25

METHOD FOR MAKING COMPOSITION

The compositions of the present invention can be produced by any method useful for forming compositions, e.g., tea bag, powder, or tablets, in pharmaceutical or food industries known in the art. Such conventional methods
30 for making powder, granules, or tablets include direct compression of ingredients and a preparation of granules before compression when the products is in tablets form.

The granulating methods useful herein include wet and dry granulating method, preferably wet granulating. Depending on the properties of the
35 ingredients (e.g., active ingredients, carriers, flavors, coloring agents, and the

like) to be formulated into granules, one method may provide a more favorable end product over the other method. The wet granulation method is widely used and usually produces the most satisfactory results in tablets. See E.J. de Jong; "The preparation of microgranulates, an improved tableting technique,"
5 Pharmaceutical Weekblad, 104(23), pages 469-474, 1969 and E.J. de Jong, U.S. Patent 3,266,992.

The tablet forms of the compositions of the present invention also can be made by any method which is conventionally used for tableting. Preferably, the tableting method includes preparation of granules by the wet granulating method
10 as described above. See, for example, Palermo, et al., U.S. Patent 3,384,546. Direct compression may also be chosen for the present composition, as long as producing tablets does not cause capping.

USE OF THE COMPOSITION

15 The composition of the present invention can be used for a variety of products in different areas, including pharmaceutical products. These products are, for example, pharmaceuticals for medical treatment of physical injuries and as aroma therapy products for inducing relaxation and stress release by being in perfumed environments. The perfumed conditions provided are also useful for
20 skin treatment. The composition of the present invention may further be used for pest control, by generating a certain toxin. The compositions are particularly useful for readily inhalation of aromatic actives and fragrance compounds for treatment of symptoms such as cold, blocked nose, and the like.

The composition of the present invention may further be suitable for
25 products designed for body warming, including for example, heating or warming pads to warm the body to enable it to release pain. The composition herein may useful to lessen the stress caused by such pains, at the time of treating the injury by warming the painful areas of the body.

The composition of the present invention may further be suitable for a kit
30 product, for example, a kit comprising two chambers wherein one chamber contains water and the other contains the composition. Such a kit is used by removing a separator located between two chambers which keeps the composition from reacting with water until the kit is used. Alternatively, a kit including a bag into which the composition is packed may be provided, the bag
35 being made from a water-impermeable material such as polymer. Such a kit is

used by breaking the bag in the presence of water. Any form of the composition may be provided in the kit.

In other embodiment of a kit, the kit comprises an effective amount of an aromatic ingredient in a first chamber, an exothermic ingredient and a pH
5 adjusting agent in a second chamber, and water in a third chamber, wherein the second chamber is next to the third chamber, such that, upon combining the second chamber and the third chamber, an exothermic reaction is generated and aroma is delivered. Such kits are also useful as products mentioned above.

The composition of the present invention take a variety of forms
10 depending on its usage. These formations can include tablet, powder or granules, and those suitable for packed into bags or containing into kits. Preferably, the form is tablet.

Tablet is a typical pharmaceutical form which is easy and convenient to use. The composition of the present invention can be compressed into the
15 tablet form. The tablet is used as follows: put the tablet in a cup into which water is contained so that the exothermic reaction proceeds and the aroma is delivered. Without being bound by theory, it is believed that due to the limited surface areas of the tablet form, the rate of the exothermic reaction tends to be slow at first, probably until the tablet is dissolved, after which the time the
20 exothermic reaction proceeds more efficiently and generation of aroma suddenly becomes harder than previous. Prior to that time, most of the reaction may occur only on the surface of the tablet. The tablet composition in tablet form tends to provide a peak temperature, about 2 minutes after contact with water, although that time depends on the diameter, thickness, and/or hardness of the
25 tablet. After achieving a peak temperature, the heat generation by the exothermic reaction is decreased, then the temperature cools down. It is believed that the most of the surface of the tablet start disintegrating, the rate of reaction becomes faster than before, resulting in sudden increase of the heat generation leading to a peak temperature. Generally, at temperatures of less
30 than about 40 degC., the aroma delivery may not be generated or there may be a lesser generation of aroma.

Powder or granules are another embodiment of the composition. The use of the powder form composition or granules is same as the tablet; put the powder or granules into a cup in which water is contained or added later, thereby
35 the aroma is delivered. It is believed that due to the higher surface area of the

powder form of the composition versus the tablets form of the composition, the rate of reaction is faster than that of the tablet composition and can deliver aroma more uniformly, *i.e.*, the temperature versus time profile is flat with no peak. In addition, the temperature generated by the reaction of the powder form composition or granules may be lower than the that of tablet form.

EXAMPLES

The following examples further describe and demonstrate embodiments within the scope of the present invention. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention, as many variations thereof are possible without departing from the spirit and scope of the invention.

The components shown below can be prepared by any conventional method well known in the art. A suitable method and formulation are as follows:

Example I A tea bag composition 1

23.54gms of calcium oxide as an exothermic ingredient, 71.86gms of Citric acid as a pH adjusting agent, 3.1 gm of menthol as an aromatic active and 1.5 gm of spearmint oil as an aromatic fragrance are mixed in a V cone blender about 30 min at 30 RPM. 5 gm of the mixture I is packed in a tea bag made from paper (tea bag 1).

Example II A tea bag composition 2

13.06 gm of magnesium as an exothermic ingredient, 78.36 gm of Citric acid as a pH adjusting agent, 7.36 gm of menthol as an aromatic active and 1.22 gm of spearmint oil as an aromatic fragrance are mixed in a V cone blender about 30 min at 30 RPM. 1 gm of the mixture II is packed in a tea bag made from paper (tea bag 2.)

Example III A powder composition 1

23.54 gm of calcium oxide as an exothermic ingredient, 70.61gm of Citric acid as a pH adjusting agent, 3.1 gm of menthol as an aromatic active and 1.5 gm of spearmint oil as an aromatic fragrance, and 1.25 gm of NaHCO₃ for an effervescent effect (to generate CO₂ gas) are blended in a V cone blender and mixed about 30 min at 30 RPM.

Example IV A powder composition 2

13.06 gm of magnesium as an exothermic ingredient, 78.36 gm of Citric acid as a pH adjusting agent, 7.36 gm of menthol as an aromatic active, and 1.22 gm of spearmint oil as an aromatic fragrance are blended in a V cone blender and mixed about 30 min at 30 RPM.

Example V A tablet composition 1

79.83 gm of 1:1 Citric acid - Sugar -granules, 13.3 gm 1:1 Magnesium - Sugar granules, and a mixture containing 2.5 gm of aerosil, 3.75 gm of menthol as aromatic active and 0.63 gm of spearmint oil as a aromatic fragrance is prepared.

The mixture of aerosil, menthol and spearmint oil is added to a Kalweka (made by Cadmac, India) in which the Sugar - Citric acid granules, Magnesium - Citric acid granules are then mixed for 20 minutes at 30 RPM.

The resulting granules are compressed on single punch machine (made by Cadmac, India) into a tablet having a diameter of 19mm.

(wt%)					
	Example I	Example II	Example III	Example IV	Example V
product type	tea bag 1	tea bag 2	powder 1	powder 2	tablet 1
calcium oxide	23.54	-	23.54	-	-
magnesium	-	13.06	-	13.06	-
Mg-granules	-	-	-	-	13.3
NaHCO ₃	-	-	1.25	-	-
Citric acid	71.86	78.36	70.61	78.36	-
Citric-granules	-	-	-	-	79.82
Menthol	3.1	7.36	3.1	7.36	3.75
Spearmint oil	1.5	1.22	1.5	1.22	0.63
Aerosil	-	-	-	-	2.5
Total	100.0	100.0	100.0	100.0	100.0

Mg-granules containing 1:1 of magnesium and sugar.

Citric-granules containing 1:1 of citric acid and sugar.

The embodiments disclosed and represented by the previous examples have many advantages. For example, they can provide effective aroma delivery that is both aesthetically and/or therapeutically desirable and convenient to use.

5 It is understood that the foregoing detailed description of examples and embodiments of the present invention are given merely by way of illustration, and that numerous modifications and variations may become apparent to those skilled in the art without departing from the spirit and scope of the invention; and such apparent modifications and variations are to be included in the scope of the appended claims.

What is claimed is:

1. A composition for delivering aroma comprising:
 - (a) an aromatic ingredient;
 - (b) an exothermic ingredient; and
 - (c) a pH adjusting agent;wherein the aroma is delivered when water is added to the composition.
2. The composition of Claim 1, wherein the composition after delivering aroma has a pH of from about 3 to about 7.
3. The composition of Claim 2, wherein the aromatic ingredient is selected from the group consisting of an aromatic active, an aromatic fragrance ingredient, and mixtures thereof; and wherein the aromatic active is selected from the group consisting of menthol, eucalyptus, campur, thymol, l-desoxyephedrine, bornyl acetate, and mixtures thereof; and the aromatic fragrance ingredient is selected from the group consisting of peppermint oil, spearmint oil, lavender oil, citronella oil, lemon oil, orange oil, sandalwood oil, and mixtures thereof.
4. The composition of Claim 3, wherein the exothermic ingredient is selected from the group consisting of a metal and a metal oxide.
5. The composition of Claim 4, wherein the composition further comprises an additional ingredient selected from the group consisting of a carrier, a effervescent agent, a binding agent, a coloring agent, a tableting aid, and mixtures thereof.
6. A composition for delivering aroma comprising:
 - (a) an aromatic ingredient selected from the group consisting of an aromatic active, an aromatic fragrance ingredient, and mixtures thereof;
 - (b) first granules comprising an exothermic ingredient and a first carrier; and

- (c) second granules comprising a pH adjusting agent and a second carrier;

wherein the aroma is delivered when water is added to the composition.

- 7. A method for making an aroma delivery composition comprising:
 - (a) combining an aromatic ingredient, an exothermic ingredient, and a pH adjusting agent and mixing the components; and
 - (b) forming a mixture of step (a) to obtain the composition of claim 1.

- 8. A method for making an aroma delivery composition comprising:
 - (a) forming first granules comprising an exothermic ingredient and a first carrier;
 - (b) forming second granules comprising a pH adjusting agent and a second carrier;
 - (c) combining the first granules and the second granules with an aromatic ingredient selected from the group consisting of an aromatic active, an aromatic fragrance ingredient, and mixtures thereof to obtain the composition of claim 6.

- 9. A kit comprising an effective amount of an aromatic ingredient, an exothermic ingredient, and a pH adjusting agent in a first chamber, and water in a second chamber, such that, upon combining the two chambers, an exothermic reaction is generated and aroma is delivered.

- 10. A kit comprising an effective amount of an aromatic ingredient in a first chamber, an exothermic ingredient and a pH adjusting agent in a second chamber, and water in a third chamber, wherein the second chamber is next to the third chamber, such that, upon combining the second chamber and the third chamber, an exothermic reaction is generated and aroma is delivered.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/05581

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K7/46 A61K9/00 A61K9/20 A61L9/02 A01N25/20
A61K9/16 A61K35/78

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K A61L A01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 598 823 A (O'GRADY) 3 June 1952 see the whole document	1-10
A	--- DATABASE WPI Week 8547 Derwent Publications Ltd., London, GB; AN 85-292289 XP002089055 & JP 60 199813 A (TANIGAKI) see abstract	1-10
A	--- DATABASE WPI Week 8733 Derwent Publications Ltd., London, GB; AN 87-230747 XP002089056 & JP 62 153216 A (JAPAN EBIAN YG) see abstract	1-10
	--- -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search

4 January 1999

Date of mailing of the international search report

26/01/1999

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INTERNATIONAL SEARCH REPORT

Inter national Application No
PCT/US 98/05581

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 695 552 A (F CUBE CO.) 7 February 1996 see the whole document ----	1-10
A	DATABASE WPI Week 9744 Derwent Publications Ltd., London, GB; AN 97-474271 XP002089057 & JP 09 220045 A (CHUGAI CHEM KOGYO KK) see abstract ----	1-10
A	US 4 913 168 A (POTTER ET AL.) 3 April 1990 see the whole document ----	1-10
A	DATABASE WPI Week 8440 Derwent Publications Ltd., London, GB; AN 84-246116 XP002089058 & JP 59 147076 A (KURARAY CO) see abstract ----	1-10
A	PATENT ABSTRACTS OF JAPAN vol. 018, no. 433 (C-1237) & JP 06 134025 A (SUNSTAR) see abstract -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/05581

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2598823 A	03-06-1952	NONE	
EP 695552 A	07-02-1996	JP 8047524 A CN 1121835 A US 5593635 A	20-02-1996 08-05-1996 14-01-1997
US 4913168 A	03-04-1990	CA 2002438 A CN 1043077 A DK 602789 A EP 0371282 A JP 2200626 A	31-05-1990 20-06-1990 31-05-1990 06-06-1990 08-08-1990

